Little Red Riding Hood and the Big Bad Wolf Revisited as Structured Content

The story of Little Red Riding Hood is used to describe the difference between content and structure, and to establish medical writers as the source of content. Content and structure are inherently different concepts, but are often mistakenly perceived as the same, despite being generated by personnel in different departments and playing a different role in submission documents. Content, as described in this article, is generated by medical writers and is the text (or document) that supplies meaning. It is the way we describe our product's safety, efficacy, and functionality to each other, to the regulatory agencies, and eventually to the general public. Structure is the table of contents or backbone that holds the content and defines organization within a document, or for a group of documents. Structure is generated by information architects and technologists. Both content and structure are essential to regulatory documentation, as most content generated requires structure for navigation and review. The volume of regulatory content is overwhelming without structure, and structure without content lacks sufficient meaning for the purposes of product description.

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INTRODUCTION

Certainly everyone remembers the story of "Little Red Riding Hood," a fairy tale notorious for the complexity of its drama and underlying themes. A story of such emotional impact and dramatic dialogue is ideal for illustration of content versus structure. These concepts are inherently different but are often mistakenly perceived as the same, despite being generated by different departments and playing a different role in our submission documents. Content is generated by authors (or medical writers) and provides detailed text, and structure is generated by information architects and technologists for the purpose of organizing content.

The story explores many of our greatest childhood fears: an innocent child leaves the safety of her village and walks alone through the woods to visit her grandmother, only to find that the grandmother is gone. In her place is a wolf dressed in the grandmother's clothing, who lures Little Red Riding Hood into bed and devours her.

The juxtaposition of safety (the village) and danger (the woods), and the terrorizing themes of abandonment, violation, sexual abuse, lost innocence, and death go right to the heart of our earliest nightmares and make this story memorable. The origins of the published story are in seventeenth-century France (1), but variations on this universal theme of our darkest childhood fears have been told for up to 2,600 years (2).

This brief story allows an easy illustration of the difference between content and structure, concepts that are applicable to our regulatory documents. All information used in our regulated environment has two fundamental characteristics: content and structure (3). These concepts will be described in terms relevant to an individual document, and also to a group of documents. Content, as described in this article, is the text (or document) that supplies meaning (4), and is the way we describe our product's safety, efficacy, and functionality to each other, to the regulatory agencies, and eventually to the general public (3). Structure is the table of contents or backbone that holds the content and defines organization within a document, or for a group of documents (5). Medical writers are the

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TABLE 1

"Little Red Riding Hood"	
Structure (or Table of Contents): Used for Navigation	**Content: Detailed Description of Action**
Title	Little Red Riding Hood
Little Red Riding Hood leaves home	Once upon a time there lived in a certain village a little country girl, the prettiest creature that ever was seen. Her mother was very fond of her, and her grandmother loved her still more. This good woman made for her a little red riding hood, which became the girl so well that everybody called her Little Red Riding Hood. One day her mother, having made some custards, said to her:— "Go, my dear, and see how your grandmother does, for I hear she has been very ill; carry her a custard and this little pot of butter." Little Red Riding Hood set out immediately to go to her grandmother's, who lived in another village.
Little Red Riding Hood meets the wolf	As she was going through the wood, she met Gaffer Wolf,* who had a very great mind to eat her up; but he dared not, because of some fagot-makers hard by in the forest. He asked her whither she was going. The poor child, who did not know that it was dangerous to stay and hear a wolf talk, said to him:— "I am going to see my grandmother, and carry her a custard and a little pot of butter from my mamma."
Wolf deceives Little Red Riding Hood	"Does she live far off?" said the Wolf. "Oh, yes," answered Little Red Riding Hood; "it is beyond that mill you see there, the first house you come to in the village." "Well," said the Wolf, "and I'll go and see her, too. I'll go this way, and you go that, and we shall see who will be there first." The Wolf began to run as fast as he could, taking the shortest way, and the little girl went by the longest way, amusing herself by gathering nuts, running after butterflies, and making nosegays of such little flowers as she met with.
Wolf arrives at grandmother's house	The Wolf was not long before he reached the old woman's house. He knocked at the door—tap, tap, tap. "Who's there?" called the grandmother. "Your grandchild, Little Red Riding Hood," replied the Wolf, imitating her voice, "who has brought a custard and a little pot of butter sent to you by mamma." The good grandmother, who was in bed, because she was somewhat ill, cried out:— "Pull the bobbin, and the latch will go up."
Wolf eats grandmother	The Wolf pulled the bobbin, and the door opened. He fell upon the good woman and ate her up in no time, for he had not eaten anything for more than three days.
Little Red Riding Hood arrives at grandmother's house	He then shut the door, went into the grandmother's bed, and waited for Little Red Riding Hood, who came sometime afterward and knocked at the door—tap, tap, tap. "Who's there?" called the Wolf. Little Red Riding Hood, hearing the big voice of the Wolf, was at first afraid; but thinking her grandmother had a cold, answered:— "Tis your grandchild, Little Red Riding Hood, who has brought you a custard and a little pot of butter sent to you by mamma." The Wolf cried out to her, softening his voice a little:— "Pull the bobbin, and the latch will go up." Little Red Riding Hood pulled the bobbin, and the door opened.
Wolf lures Little Red Riding Hood into bed	The Wolf, seeing her come in, said to her, hiding himself under the bedclothes:— "Put the custard and the little pot of butter upon the stool, and come and lie down with me." Little Red Riding Hood undressed herself and went into bed, where she was much surprised to see how her grandmother looked in her night-clothes. She said to her:— "Grandmamma, what great arms you have got!" "That is the better to hug thee, my dear."

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TABLE 1

Continued	
	"Grandmamma, what great legs you have got!" "That is to run the better, my child." "Grandmamma, what great ears you have got!" "That is to hear the better, my child." "Grandmamma, what great eyes you have got!" "It is to see the better, my child." "Grandmamma, what great teeth you have got!" "That is to eat thee up."
Wolf eats Little Red Riding Hood	And, saying these words, this wicked Wolf fell upon Little Red Riding Hood, and ate her all up.

*Although the meaning and origin of the word *gaffer* is not clear, it is thought to be a contraction of godfather or grandfather, and may imply a close family relation. The modern definition is "an old man, or a rustic" (6), but considering the complexity of folklore terminology and interpretations, it may imply incest. Lack of suspicion and fear when getting into bed with the wolf has been a constant in virtually all versions of the story. A possible explanation is that Little Red Riding Hood thought she was climbing in with her grandfather, who would have been expected to be in bed with the grandmother (7).

source for content, and information architects and technologists are the source for structure.

LITTLE RED RIDING HOOD

A version of "Little Red Riding Hood" written in 1697 by Charles Perrault is considered to be the first published account of the story (1). I have selected this story for discussion of how content and structure within an individual document differ, yet are complementary and greatly enhance each other when used effectively together (Table 1, Figure 1). As we will see, structure, which can be thought of as the table of contents, guides the reader through the story, using brief text that hints at the content within. Content is where the interesting and expanded details reside.

CONTENT VERSUS STRUCTURE

This simple fairy tale allows a clear perspective on the difference between content and structure in a document. If viewing the structure (or table of contents) of this story, we will have an accurate and succinct picture of the story line:

- Little Red Riding Hood leaves home.
- Little Red Riding Hood meets the wolf.
- Wolf deceives Little Red Riding Hood.
- Wolf arrives at grandmother's house.
- Wolf eats grandmother.
- Little Red Riding Hood arrives at grandmother's house.
- Wolf lures Little Red Riding Hood into bed.
- Wolf eats Little Red Riding Hood.

Although accurate as a means of navigating through the story, just as one would use the table of contents of an investigator brochure to navigate, the structure (by design) lacks sufficient detail to convey the dramatic content. For example, this structure is completely devoid of the most exciting part of this story—the conversation with the wolf. Content is required to provide an expanded explanation for the sheer terror alluded to in the structured line "Wolf lures Little Red Riding Hood into bed." At this point in the story, the wolf has convinced the little girl to take off her clothing and get into bed with him, and through their shared dialogue we anticipate the approach of the final act of the story—the wolf devouring Little Red Riding Hood.

FIGURE 1

"Oh, granny, your teeth are tremendous in size!" "They're to eat you!" and he ate her (11).

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TABLE 2

Outline of the Investigator Brochure	
1	Table of Contents
2	Summary
3	Introduction
4	Physical, Chemical, and Pharmaceutical Properties and Formulation
5	Nonclinical Studies
5.1	Nonclinical Pharmacology
5.2	Pharmacokinetics and Product Metabolism in Animals
5.3	Toxicology
6	Effects in Humans
6.1	Pharmacokinetics and Product Metabolism in Humans
6.2	Safety and Efficacy
6.3	Marketing Experience
7	Summary of Data and Guidance for the Investigator

Content is the detailed description that provides meaning. Medical writers are responsible for providing clear, useful, and accurate information in the form of content that is essential to product approval, marketing, and use by our customers, that is, physicians and patients (8). Conceptually, content is independent of software or any other electronic conventions, although in our industry, medical writers generate content using software. In the case of this fairy tale, content has been independent of everything except paper and ink for at least three centuries (1).

Structure is the table of contents or backbone that holds the content and defines organization within a document. Although the structure includes a few words, the severely abbreviated nature of this text relegates these words to a description that aids navigation for the purpose of finding content—it is not content in and of itself. Structure also may be independent of software (as it is here in our story), but in our modern world of electronic publishing, structure may consist of a predefined and consistent organization of information, usually inextricably intertwined with an XML-based software program that automatically formats text (5).

A document structure we are all familiar with is found in the investigator's brochure (9). The table of contents as described in ICH E6 is presented in Table 2, and shows how the structure helps the reader to navigate but does not provide any essential details (or content) such as the pharmaceutical properties, toxicity, or clinical risk.

The concept of structure can be extrapolated to include a group of documents organized by a structured backbone. In this case, each document is considered to be content. The structured backbone consists of software files, often XML, that hold and organize the documents, which are generally in portable document file (PDF) format (10). The combination of a structured backbone and PDF documents is used to generate electronic submissions to regulatory authorities.

Structure and content in a regulatory environment not only differ conceptually but are generated by different departments and by staff with different skill sets. Both content and structure are essential to regulatory documents but serve completely separate purposes. Content is generated by medical writers for the clinical, nonclinical, quality (manufacturing), or marketing departments within the pharmaceutical and medical device industries (3). Structure, because it is based on software, and particularly if pertaining to the structure used to organize a group of documents, is under the purview of information architects and technologists, which may include electronic publishing personnel (3).

CONCLUSION

Content is generated by medical writers and structure is generated by information specialists. Both content and structure are essential to regulatory documentation, as most of the content generated requires structure for navigation and review. The volume of regulatory content is overwhelming without structure, and structure

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without content lacks sufficient meaning for the purposes of product description.

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